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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,566	02/23/2006	Brian A. Whittle	187287/US/DJB/VEJ	3673

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EXAMINER	
COLLINS, MICHAEL	
ART UNIT	**PAPER NUMBER**
3651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,566	WHITTLE ET AL.	
	Examiner	Art Unit	
	Michael K. Collins	3651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 January 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "23", "24", "28". Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15-16, and 18-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

- Claim 15 discloses, "A reservoir as claimed in claim 1, for use in the dispenser of claim 1." Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness. Furthermore claim 1 is directed to a "machine". Therefore claim 15 is directed to neither a "process" nor a "machine," but rather embrace or overlap two statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. See, MPEP, section 2173.05(p)-(q).
- Claim 16 discloses, "A method of making a dispenser as defined in claim 1, comprising introducing the plurality of dosage units into the reservoir and then sealing the reservoir in the dispenser so as to render the dispenser tamper-evident." Claim 1 is directed to a "machine". Therefore claim 16 is directed to neither a "process" nor a "machine," but rather embrace or overlap two statutory

classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. See, MPEP, section 2173.05(p).

- Claim 18 discloses, "A controlled method of taking a drug of abuse or a controlled drug comprising administering said drug of abuse or controlled drug from a dispenser as defined in claim 1." Claim 1 is directed to a "machine". Therefore claim 16 is directed to neither a "process" nor a "machine," but rather embrace or overlap two statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. See, MPEP, section 2173.05(p). In particular, 18-19 recite both a process and a machine.
- Claim 20 discloses, "Use of a drug of abuse or a controlled drug in the manufacture of a medicament for use in a controlled method of taking a drug of abuse or controlled drug comprising administering said drug of abuse or controlled drug from a dispenser as defined in claim 1." Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness. Furthermore claim 1 is directed to a "machine". Therefore claim 20 is directed to neither a "process" nor a "machine," but rather embrace or overlap two statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. See, MPEP, section 2173.05(p)-(q). In particular, 20-21 recite both a process and a machine.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16, and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

More specifically, MPEP, section 2173.05(p) states, "A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph." Id. Claims 16, 18, and 20 and the dependent claims 19 and 21 recite the **machine** including a delivery device, i.e. the dispenser, and a **method** of making... and of taking... Since claims 16, 18, 20 and the dependent claims 19 and 21 claim both an apparatus and the method steps of using the apparatus, these claims are indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Haitin et al. (USP 7,155,306).

Regarding claim 1, Haitin et al. disclose a dispenser (30) comprising a reservoir (130a) containing a plurality of dosage units each of which comprise a formulation of a controlled drug or drug of abuse, said dosage units being contained in a tamper-evident manner such that access to the dosage units in use is controlled either by the dispenser or remotely and/or is monitored either by the dispenser or remotely (see column 6 lines 39-59, and column 7 lines 16-34).

Regarding claim 2, Haitin et al. disclose the dispenser as claimed in claim 1, wherein the controlled drug or

drug of abuse is a class A drug in a non-intravenous formulation, as defined by The Misuse of Drugs Act 1971.

Regarding claim 3, Haitin et al. disclose the dispenser as claimed in claim 1, wherein the controlled drug or drug of abuse is an opioid.

Regarding claim 4, Haitin et al. disclose the dispenser as claimed in claim 1, wherein the opioid is methadone or a pharmaceutically acceptable salt or derivative thereof.

Regarding claim 5, Haitin et al. disclose the dispenser as claimed in claim 4, wherein the opioid is methadone hydrochloride.

Regarding claim 6, Haitin et al. disclose the dispenser as claimed in claim 4, wherein the formulation is for oral delivery.

Regarding claim 7, Haitin et al. disclose the dispenser as claimed in claim 1, wherein the opioid is diamorphine or a pharmaceutically acceptable salt or derivative thereof.

Regarding claim 8, Haitin et al. disclose the dispenser as claimed in claim 7, wherein the opioid is diamorphine hydrochloride.

Regarding claim 9, Haitin et al. disclose the dispenser as claimed in claim 7, wherein the formulation is dry and suitable for nasal delivery upon mixing with an aqueous solution.

Regarding claim 10, Haitin et al. disclose the dispenser as claimed in claim 9, wherein the formulation further comprises a solubility enhancer.

Regarding claim 11, Haitin et al. disclose the dispenser as claimed in claim 10, wherein the solubility enhancer is one or more of caffeine, sodium benzoate and sodium salicylate.

Regarding claim 12, Haitin et al. disclose the dispenser as claimed in claim 10 wherein the solubility enhancer comprises caffeine and sodium benzoate and/or sodium salicylate.

Regarding claim 13, Haitin et al. disclose the dispenser as claimed in claim 9, wherein said formulation is a freeze-dried formulation.

Regarding claim 14, Haitin et al. disclose the dispenser as claimed in claim 1, wherein more than 1 day's supply of dosage units are contained in the dispenser.

Regarding claim 15, Haitin et al. disclose a reservoir as claimed in claim 1, for use in the dispenser of claim 1.

Regarding claim 16, Haitin et al. disclose a method of making a dispenser as defined in claim 1, comprising introducing the plurality of dosage units into the reservoir

and then sealing the reservoir in the dispenser so as to render the dispenser tamper-evident (see column 7 lines 16-34).

Regarding claim 17, Haitin et al. disclose a formulation as defined in claim 9.

Regarding claim 18, Haitin et al. disclose a controlled method of taking a drug of abuse or a controlled drug comprising administering said drug of abuse or controlled drug from a dispenser as defined in claim 1.

Regarding claim 19, Haitin et al. disclose a method as claimed in claim 18, wherein said drug of abuse or controlled drug is present in a formulation as defined in claim 9.

Regarding claim 20, Haitin et al. disclose use of a drug of abuse or a controlled drug in the manufacture of a medicament for use in a controlled method of taking a drug of abuse or controlled drug comprising administering said drug of abuse or controlled drug from a dispenser as defined in claim 1.

Regarding claim 21, Haitin et al. disclose use as claimed in claim 20, wherein said drug of abuse or controlled drug is present in a formulation as defined in claim 9.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haitin et al. (USP 7,155,306) as applied to claims 1-21 above, and further in view of Castellano et al. (USP 5,593,390).

Regarding claim 22, Haitin et al. disclose a dispenser as claimed in claim 9. However, they do not disclose a kit of parts comprising an aqueous liquid for introduction into the dispenser for rendering the formulation suitable for nasal administration. Castellano et al. disclose a kit of parts comprising an aqueous liquid for introduction into the dispenser for rendering the formulation suitable for nasal administration. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the applicant's invention to modify Haitin et al. by including with the dispenser a kit of parts comprising an aqueous liquid for introduction into the dispenser for rendering the formulation suitable for nasal administration, as disclosed by Castellano et al., for the purpose of delivering the medication via nasal spray (see column 23 lines 27-40).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael K. Collins whose telephone number is (571) 272-8970. The examiner can normally be reached on 8:30 am - 5:00 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene O. Crawford can be reached on (571) 272-6911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M.C.
4/25/2007

GENE O. CRAWFORD
SUPERVISORY PATENT EXAMINER